REMARKS/ARGUMENTS

In response to the Final Office Action mailed March 26, 2010, Applicants propose to amend their application and request reconsideration in view of the proposed amendments and the following remarks. In this amendment, Claim 1 is proposed to be amended, no claims have been added, or cancelled without prejudice, and claims 9 and 10 have been previously withdrawn so that Claims 1, 4, 5, and 9-10 are currently pending. No new matter has been introduced.

Claims 1, 4 and 5 were rejected under 35 USC 112, first paragraph. Applicants have amended the claims to be consistent with the specification, specifically paragraphs [0498] and [0499] as well as Table 9.0. Taking the date from the first row of Table 9, we can calculate the amount of each claimed element in the formulation. The total amount included in the formulation would be 202.7 mg of sirolimus plus 642 mg of vitamin E TPGS plus 230 mg ethanol plus 320 mg of vitamin E TPGS and 13,300 mg water both from column 5 of Table 9 (equivalent to 13.3 ml water) which is equal to 14,694.70 mg. This is now our denominator to calculate the percentages of each. The percent of ethanol would be (230 mg/14,694.7mg) x 100 = 1.57 %. The percent of vitamin E TPGS would be ((642mg + 320mg)/14,694.7 mg) x 100 = 6.55 %. The percent of water would be (13,300mg/14,694.7mg) x 100 = 90.51 %. These are the correct numbers and are supported by the specification. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1, 4 and 5 were rejected as being unpatentable over EP0041795A2 to Sehgal in view of U.S. Patent Publication No. 2004/0167152 to Rubino et al. (Rubino). This rejection is respectfully traversed.

In order to make a finding of obviousness, an Examiner must (1) determine the scope and content of the prior art, including non-analogous art if it is in the field of endeavor reasonably related to the particular problem to which the claimed

invention is directed, (2) ascertain the differences between the claimed invention and the prior art, considering both the prior art and claimed invention as a whole, and (3) resolve the level of ordinary skill in the art at the time of the invention, factoring in the creativity that one of ordinary skill in the art would employ as well as the Examiner's own knowledge and technical expertise.

It is respectfully submitted that the references taken as a whole fail to disclose or suggest all of the claimed limitations.

Sehgal discloses an injectable composition of rapamycin. The composition provides for 1 to 20 milligrams of rapamycin per milliliter of the composition and a nonionic surfactant. Various concentrations are illustrated. The injectable rapamycin composition comprises rapamycin, a nonionic surfactant and water. Upon removal of the solvent, the rapamycin remains in solution in the nonionic surfactant. Dilution of the above solutions containing rapamycin, solvent and nonionic surfactant or rapamycin and nonionic surfactant are made with water.

Rubino discloses parenteral formulations of rapamycin 42-ester with 3-hyroxy-2-(hydroxymethyl)-2-methyl-propionic acid. Essentially, this patent publication discloses solubilizing CCI-779 with a parenterally acceptable co-solvent accompanied by the presence of an antioxidant and/or chelating agent in the solution. Parenteral generally refers to a means of administration that involves piercing the skin or mucous membrane, typically via injection.

Neither of the references, whether taken alone or in combination disclose or suggest the invention of independent claim 1. Sehgal discloses multiple formulations of an injectable composition of rapamycin. In one composition there is rapamycin plus Cremophor EL. In another composition there is rapamycin plus 8 % ethanol, 32 % propylene glycol, 10 % Cremophor RH and 50 % water. There is also a composition comprising rapamycin, Butylated hydroxyanisole, Benzyl alcohol, Cremaphor EL and

water. Rubino also fails to disclose a water based solution. Therefore, none of the references, whether taken alone or in combination, discloses or suggests the unique formulation as claimed in amended claim 1. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Applicant would be grateful for the opportunity to conduct a telephonic or in-person interview of the Examiner believes it would be helpful in disposing of the present case.

A favorable action on the merits is earnestly solicited.

Respectfully submitted,

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